

REMARKS/ARGUMENTS

Claims 9-25 are cancelled; Claims 26-34 are new.

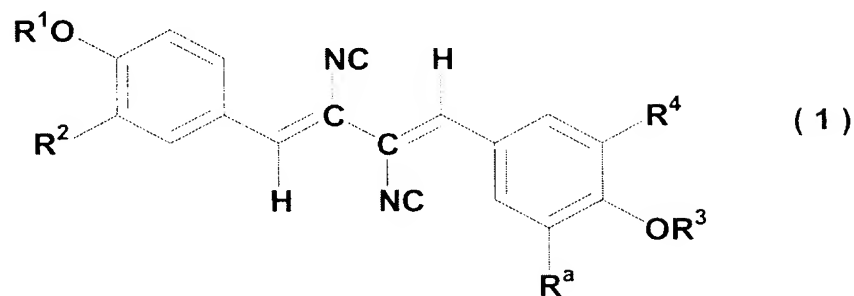
Support for the “in need thereof” feature of Claims 1-9 is found, for example, at specification page 25. Support for the feature of Claims 26-34, that “the compound of formula (1) or its salt does not comprise the compound of formula (2) or its salt,” is found, for example, at specification page 38, first compound, top, right hand side, in combination with M.P.E.P. § 2173.05(i) which describes, in part, that “[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.”

Support for Claim 27 is found, for example, at Claim 1. Support for Claim 28 is found, for example, at Claim 2. Support for Claim 29 is found, for example, at Claim 3. Support for Claim 30 is found, for example, at Claim 4. Support for Claim 31 is found, for example, at Claim 5. Support for Claim 32 is found, for example, at Claim 6. Support for Claims 33 and 34 is found, for example, at Claim 7.

No new matter is added.

The anticipation rejection of Claims 1-8 as being unpatentable in view of Tsuruoka is respectfully traversed.

Present Claim 1 is drawn to a method of increasing platelets in a human in need thereof (emphasis added). The method comprises administering an isolated compound or its salt to the human in need thereof in an amount sufficient to increase the platelets in the human in need thereof (emphasis added). The isolated compound or its salt is represented by the formula (1) or its salt,



, with the groups R¹, R², R³, R⁴ and R^a being defined in Claim 1, *supra*.

Applicants traverse the anticipation rejection because Tsuruoka does not describe or suggest the present Claim 1 method of increasing platelets in a human in need thereof; the method comprising administering an isolated compound or its salt to the human in need thereof in an amount sufficient to increase the platelets in the human in need thereof (emphasis added).

Tsuruoka describes “[t]umor growth in a mammal is inhibited by the administration of an effective amount of xanthocillin X dimethyl ether. The xanthocillin X dimethylether is administered in a range of 10-3,000 milligrams per day for an average adult patient” (see the Abstract of Tsuruoka. Thus, Tsurouka is drawn to administering xanthocillin X dimethyl ether to inhibit tumor growth. Tsurouka does not describe or suggest a method of increasing platelets in a human in need thereof; the method comprising administering an isolated compound or its salt to the human in need thereof in an amount sufficient to increase the platelets in the human in need thereof, as found in present Claim 1 and the claims depending therefrom.

The “in need thereof” language used here has been approved by the Federal Circuit for inventions like present Claim 1 where the method requires the specific intent to effect the specific results stated in the preamble of the claim.

The case of Jansen v. Rexall Sundown Inc., 68 U.S.P.Q.2d 1154 (Fed. Cir. 2003) requires that the currently pending prior art rejection be withdrawn. In *Jansen*, the claims

were directed to methods of treating or preventing macrocytic-megaloblastic anemia comprising administering effective amounts of folic acid and vitamin B₁₂ to humans in need thereof. *Jansen* at 1157. In interpreting these claims, the Federal Circuit ruled that the claims require the specific intent to achieve the claimed objective (treatment or prevention of macrocytic-megaloblastic anemia). Specifically, the Federal Circuit stated that:

. . . the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone ‘in need.’ In both cases, the claims’ recitation of a patient or a human ‘in need’ gives life and meaning to preambles. [Citation omitted]. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated.

Rather, **it is a statement of the intentional purpose for which the method must be performed**. We need not decide whether we would reach the same conclusion if either of the ‘treating or preventing’ phrase or the ‘to a human in need thereof’ phrase was not a part of the claim; **together, however, they compel the claim construction arrived at by both the district court and this court**.

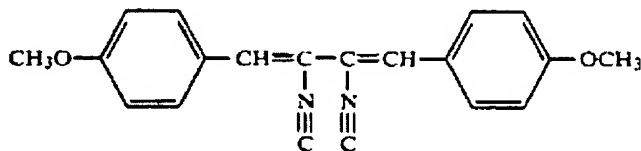
Jansen at 1158 (emphasis added).

Thus, according to the Federal Circuit, claims directed to methods of treatment to be performed on those in need of such treatment require the specific intent to effect such treatment.

Present Claim 1 is analogous to the claims in *Jansen* and is directed to a method for increasing platelets in a human in need thereof, the method comprising administering an isolated compound of formula (1) or its salt to the human in need thereof in an amount sufficient to increase the platelets in the human in need thereof... (see Claim 1, *supra*). *Tsuruoka* neither teaches nor suggests such specific intent: that is, *Tsuruoka* does not

describe or suggest administering an isolated compound of formula (1) or its salt to a human in need thereof in an amount sufficient to increase the platelets in the human in need thereof.... Thus, nothing in Tsuruoka would lead one skilled in the art to believe that the compound of formula (1) or its salt could be administered for this express purpose. Thus, Tsurouka cannot anticipate or render obvious present Claim 1 and the claims depending therefrom. Withdrawal of the anticipation rejection is respectfully requested.

Further, the Office has reasoned, at page 3 of the Official Action, that “Tsuruoka et al., disclose the use of compounds identical to the current compounds for treating patients with cancer...” (emphasis added). Applicants respectfully note that Tsuruoka discloses only one compound, xanthocillin X dimethylether, whose structure, given in column 1 of Tsuruoka, is reproduced below:



Applicants note that Claims 26-34 exclude Xanthocilin X dimethylether and its salt; accordingly, these claims cannot be anticipated by Tsuruoka.

Applicants submit the present application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

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